

DSJ1&2-PR Exh 599

From: Norton, Rita on behalf of "Norton, Rita" <RNorton@amerisourcebergen.com>
Sent: Tue, 27 Dec 2016 13:16:28 -0500 (EST)
To: "Weissman, Gabriel" <GWeissman@amerisourcebergen.com>; "Moyer, Lauren E" <LMoyer@amerisourcebergen.com>; "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>; "May, David" <DMay@amerisourcebergen.com>
Cc: "Heller, Stacie" <SHeller@amerisourcebergen.com>; Brad Tallamy <BTallamy@amerisourcebergen.com>
Subject: FW: Industry talking points
Attachments: Industry talking points on opioid abuse 11 06 FINAL.DOCX;ATT00001.htm

Here is what we are using – trying to head off congressional response like last time if possible

From: Freitas, Kristen [mailto:kfreitas@hda.org]
Sent: Friday, December 23, 2016 2:02 PM
To: Norton, Rita
Subject: Fwd: Industry talking points

Here is the document.

Begin forwarded message:

From: "Kelly, Patrick" <pkelly@hda.org>
Date: November 16, 2016 at 10:00:02 PM EST
To: "norton@amerisourcebergen.com" <norton@amerisourcebergen.com>
Cc: "Freitas, Kristen" <kfreitas@hda.org>
Subject: Fw: Industry talking points

Rita,

Not sure my previous email got thru from my phone. Hopefully the attached Word Document is accessible.

As agreed upon by the companies that crafted these talking points - this is not a public document and is not intended to be a leave behind. These are simply agreed upon talking points to be used by staff in settings where we are called upon to explain the role of distributors.

Patrick

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INDUSTRY TALKING POINTS ON OPIOID ABUSE
DRAFT
11 06 16

Industry talking points on opioid abuse

11/6/2016

DOCUMENT OBJECTIVE

This document is intended to serve as an omnibus version of our talking points; it is not intended to be used in its entirety or left as a leave-behind. Talking points should be tailored as needed for use with various stakeholder audiences.

Based on the audience, we will rely upon the professionalism of our teams to determine when and where to deploy these points and which ones will require additional support or reinforcement.

SCOPE OF EPIDEMIC

- According to the Substance Abuse and Mental Health Services Administration (SAMHSA), nearly one in ten Americans over the age of 12 has experienced addiction to drugs or alcohol.
- Drug addiction, especially addiction to prescription opiates, is a public health crisis with multiple causes and no easy solutions.
- While opioid pain medications are necessary and appropriate in the medical care of patients who legitimately need them, opioids are tightly controlled because they are subject to misuse which can lead to addiction.

COLLABORATION IS KEY

- Substance abuse is a multi-faceted problem that cannot be solved by focusing on individual parts of the system; it must be addressed through a multi-faceted approach that includes the doctors who write the prescriptions, the pharmacists who fill them, the distributors who fill and deliver pharmacies' orders, the manufacturers who make and promote the products and the regulators who license the above activities and determine supply.
- Doctors, pharmacists, distributors, manufacturers, and regulators share the responsibilities for controlling the availability of opioid pain medications.
- National efforts to address prescription drug abuse prevention must balance the competing needs to combat the diversion of medicines for illegitimate use and the need to avoid nonessential disruptions that create shortages for patients with legitimate medical needs.

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- Pharmaceutical distributors are part of the pharmaceutical supply chain and play an important role in helping to identify and prevent prescription drug abuse and diversion. Because distributors do not manufacture or promote these products, license registrants, write prescriptions nor dispense medicines, an effective solution necessarily requires close coordination by all parties who affect the legitimate flow of these medications.

INDUSTRY ACTIONS

- As pharmaceutical distributors, we take our role in the pharmaceutical supply chain seriously. We fulfill orders *only* from entities licensed by the DEA and the Boards of Pharmacy for the individual states for prescriptions written by medical professionals licensed by regulators to prescribe these medications.
- We go to great lengths to eliminate diversion within our part of the supply chain, including the management of robust anti-diversion programs and processes to cease distributions to pharmacies with suspicious ordering patterns:
 - Every controlled substance order made to a distributor (both orders that are filled and orders that are deemed suspicious and stopped) is reported to the DEA by distributors.
 - All major distributors have dedicated employees that utilize advanced analytics, technology, and the deployment of internal and external investigators to monitor, identify and eliminate diversion.
- We are doing our part [all that we can] to address the changing threat of diversion, but to ultimately be successful in these efforts, we need the involvement, coordination and collaboration of the entire supply chain and regulators.
 - Distributors have no access to patient information or prescriber information and need to balance providing access to needed medications while taking all efforts to eliminate diversion of these same medications for inappropriate use.
- While controlled substances such as opiate pain relievers are only a very small percentage of the pharmaceutical products delivered via distributors, the industry devotes millions of dollars, develops state-of-the-art programs, and hires highly trained personnel to prevent their diversion for illegitimate purposes.
- While the issue of supply is a major factor around opioid abuse, addiction is the root cause of this epidemic and an effective solution requires a multi-faceted approach, including attacking demand through education, prevention, intervention, treatment and recovery. Distributors have created multiple education and prevention programs to help address some of the roots causes of addiction.

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THE DEA'S OVERSIGHT AND 2015 SHIFT IN APPROACH TO DISTRIBUTOR OVERSIGHT

- Federal law and DEA regulations have created a system where patients with legitimate needs can obtain appropriately prescribed medicines, but bad actors that divert those medicines for illegitimate uses can be identified and stopped.
- Distributors are required to – and all of them do – have robust controls in place to monitor controlled substance ordering, report suspicious activity and – when appropriate – cut off the supply of product to customers when they see “red flags” of possible drug diversion.
- A GAO report published in 2015 noted that enhanced communication, coordination and collaboration between the DEA and supply chain stakeholders was one of the keys to successfully mitigating prescription drug abuse and diversion.
- The DEA has changed its approach to enforcement over the past few years, combating the changing tactics of those determined to bypass the system and obtain opioids illegally.
- In June 2016, Acting Head of the DEA, Chuck Rosenberg, testified before Congress that the DEA needs distributors to partner with the DEA diversion prevention efforts, noting that the agency has historically alienated these stakeholders.
- The DEA's current strategy is to work with registrants to actively clarify ambiguities in the regulations before they become a problem. The DEA is laying the groundwork for an even more collaborative approach to solving the opioid abuse epidemic in exactly the way that the GAO recommended in 2015, including issuing rulemaking that clarifies further the responsibilities of distributors.

For Background Use Only:

- The DEA's approach from 2006-2015 was to take action against distributors for compliance issues that posed little or no patient safety risk. In some cases, the enforcement and fine were done retroactively; coming many years after the alleged violation had been corrected.
- During this same time period, the DEA refused to respond to legitimate compliance questions from distributors, did not issue any guidance or rulemaking, and refused to meet with industry to clarify its interpretation of the compliance rules.
- From 2006 to 2015, when, according to an October 2016 article in *The Washington Post*, the DEA was aggressively pursuing wholesalers, the abuse problem got meaningfully worse and the number of opioid-related deaths skyrocketed.

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- Recognizing that this approach was proving ineffective and doing nothing to meaningfully curb diversion, the DEA changed its approach in 2015. (This coincided with a change in personnel at the Office of Diversion Control)
- It's the "community policing" model of enforcement that focuses on preventing non-compliance rather than sitting back and waiting to prosecute it. Again, this approach is a clear nod to the importance of collaboration and shared responsibility from all stakeholders to addressing the scourge of opioid abuse.

S. 483 (THE ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT) CODIFIES THE DEA'S NEW APPROACH

- Congress enacted the Ensuring Patient Access and Effective Drug Enforcement Act (S. 483) without dissent six months ago, addressing the critical importance of information sharing and collaboration in successfully addressing the constantly changing methods used by abusers. Opioid abuse is an extremely complex issue, which demands that all stakeholders work together to find solutions. The more we can share information, data and ideas and collaborate on solutions, the more success we will have in the fight against opioid abuse.
- This law was specifically designed to foster cooperation among some of the key legitimate parties in this fight, to ensure that new diversion tactics and bad actors are identified and addressed as quickly as possible while creating minimal impact to legitimate patients with serious medical needs.
- Under the new law, the DEA remains fully empowered to take immediate action against a registrant if there is "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur..."
- However, in circumstances where there is a lack of regulatory clarity around a registrant's roles and responsibilities, and the public's health is not in danger, the corrective action plan provides a registrant 30 days to adequately address the DEA's concerns and to avoid having their registration revoked.
- Fundamentally, the law creates a balance between ensuring that the public is protected from potential for harm while limiting actions that could prevent appropriate access to necessary medications. The DEA and registrant can engage in a meaningful dialogue about legitimate administrative discrepancies, such as recordkeeping or monitoring. It is important to note that DOJ and DEA were integrally involved in the development of the legislation as enacted.

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RESPONSE TO LITIGATION-RELATED QUESTIONS

- Although the industry does not typically address specific matters of ongoing litigation, we believe that it is important to work diligently with regulators to continuously enhance and improve systems as we all face a devious criminal element determined to thwart the best efforts of the industry and enforcement agencies.
- We do not believe that litigation against distributors is the solution for an epidemic with such complicated, varied roots. While we recognize our role in addressing this issue, we believe that we have been responsible players in the pharmaceutical supply chain and, therefore, have no choice but to defend ourselves against allegations in court as appropriate.
- Distributors consistently enhance systems and processes to deal with the evolving tactics of the criminal element who are constantly adapting their methods to secure illegal sources of opiates.